



United States
Environmental Protection Agency
 Washington, DC 20460

☒ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number 67979- RL	2. EPA Product Manager Alan Reynolds	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) Bt11 x MIR162 x TC1507 Corn	PM # BPPD	
5. Name and Address of Applicant (Include ZIP Code) Syngenta Seeds, Inc. P.O. Box 12257, 3054 East Cornwallis Road Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section – II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Application for registration of a new end-use product containing the plant-incorporated protectants Cry1Ab, Vip3Aa20 and Cry1F, and the genetic materials necessary for their production in corn.

PROPOSED FEE CATEGORY IS 'B880'. The pesticide registration service fee for this category is \$27,563.

Section – III

Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Henry-York Steiner, Ph. D.	Title Regulatory Affairs Manager	Telephone No. (Include Area Code) (919) 541-8652	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Manager		
4. Typed Name Henry-York Steiner Tel. (919) 541-8652	5. Date January 29, 2010		



January 29, 2010

Document Processing Desk (APPL)
Office of Pesticides Programs (7511P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Alan Reynolds
Biopesticides and Pollution Prevention Division

Re: Application for registration of Bt11 x MIR162 x TC1507 corn

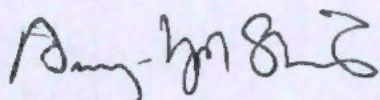
Dear Mr. Reynolds:

Please find enclosed our application for registration of the new plant-incorporated protectant (PIP) product, Bt11 x MIR162 x TC1507 corn. Bt11 x MIR162 x TC1507 corn is a combined insecticidal trait hybrid producing the Cry1Ab, Vip3Aa20 and Cry1F proteins from *Bacillus thuringiensis*. This combined trait product is produced by conventional breeding crosses of event Bt11 corn and event MIR162 with event TC1507 corn. Event Bt11, MIR162 and TC1507 are registered PIPs and as such, the requested regulatory action should fall under fee category B880 (9 month review). The appropriate PRIA fee has been paid under invoice No. 11202756300.

This application relies on safety assessments that have already been conducted by EPA for the single trait parental events, Bt11, MIR162 and TC1507. Data supporting these earlier assessments are referenced in the enclosed Data Matrix. A data citation letter from Dow AgroSciences, Inc. (DAS) is included with this application which grants the US EPA access to the data supporting the prior safety assessment of TC1507. Accordingly, the data supporting TC1507 is referenced in the Data Matrix without specific reference to MRID No.'s as instructed by BPPD staff. Tolerance exemptions exist for each of the insecticidal proteins contained in this combined trait product. Data volumes being submitted with this application or referenced by citation, characterize the genetic insert in Bt11 x MIR162 x TC1507, quantify the levels of Cry1Ab, Vip3Aa20 and Cry1F (as well as PAT and PMI) being produced, demonstrate product efficacy, address ecological risk, and describe an insect resistance management plan.

This application is comprised of ten volumes with Volume 1 containing administrative materials transmittal document and a product label. Three copies of each volume are being submitted. Should you have any questions regarding this application please contact me directly at 919-541-8652. Thank you in advance for your review and acceptance of this application.

Sincerely,

A handwritten signature in black ink, appearing to read "Henry-York Steiner".

Henry-York Steiner, Ph. D.
Regulatory Affairs Manager
Syngenta Seeds, Inc.

cc: Larry Zeph, Syngenta
Dennis Ward, Syngenta



Volume 1

Administrative Materials in Support of the Application for Registration of the Plant-incorporated Protectants in Bt11 x MIR162 x TC1507 Corn

Author

Henry-York Steiner, Ph. D.

Submission Date

January 29, 2010

Submitter

**Syngenta Seeds, Inc.
P.O. Box 12257
3054 East Cornwallis Road
Research Triangle Park, NC 27709
USA**

Submitter Reference No.

Bt11xMIR162xTC1507-EPA-1

Volume 1 of 10

Statement of Data Confidentiality Claim

Confidentiality statement for submissions to the United States Environmental Protection Agency:

A claim of confidentiality is being made for information in this volume on the basis of its falling within the scope of FIFRA 10(d)(1)(A), (B), or (C). This material is being submitted to EPA according to method and format specifications contained in PR Notice 86-5 and 40 CFR §158.33.

The data are the property of Syngenta Seeds Inc. and, as such, are considered to be confidential for all purposes other than compliance with the regulations implementing FIFRA Section 10.

Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality that may exist under any other provision of common law or statute or in any other country.

Confidentiality statement for submissions to regulatory agencies other than EPA in the U.S. (and all other viewers):

This document contains information which is proprietary to Syngenta and, as such, is considered to be confidential for all purposes other than compliance with the relevant registration procedures.

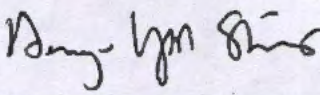
Without the prior written consent of Syngenta, it may (i) not be used by any third party including, but not limited to, any regulatory authority for the support of registration approval of this product or any other product, and (ii) not be published or disclosed to any third party including, but not limited to, any authority for the support of registration approval of any products.

Its submission does not constitute a waiver of any right to confidentiality that may exist in any other country.

Company: Syngenta Seeds, Inc.

Company

Agent:


Henry-York Steiner, Ph. D.
Regulatory Affairs Manager

Date: January 29, 2010

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TRANSMITTAL DOCUMENT

Submitter

**Syngenta Seeds, Inc.
P.O. Box 12257
3054 E. Cornwallis Road
Research Triangle Park, NC 27709**

Regulatory Action in Support of Which This Document is Submitted

**Registration for a Plant-incorporated Protectant Pursuant to FIFRA §3(c)(7)(C):
Bacillus thuringiensis Cry1Ab, Vip3A and TC1507 Proteins and the Genetic
Material Necessary for Their Production in Bt11 x MIR162 x TC1507 Corn**

EPA File Symbol 67979-__

Transmittal Date

January 29, 2010

Applicant Reference No.

Bt11xMIR162xTC1507-EPA-1

List of Accompanying Volumes

Vol.	Category ¹	Volume/Study Title	MRID
1	A	Steiner, H-Y. (2009). Administrative materials in support of the application for registration of the Cry1Ab, Vip3Aa20 and Cry1F plant-incorporated protectants in Bt11 x MIR162 x TC1507 corn. Bt11 x MIR162 x TC1507-EPA-1	
2	B	Burroughs, J., Long, N. (2009). Event Bt11 x MIR162 x TC1507 x GA21 Corn: Comparative Southern Blot Analysis. SSB-106-10	
3	B	Bednarcik, M. (2009) Comparison of Transgenic Protein Concentrations in Event Bt11, Event MIR162, Event TC1507, Event GA21, and Bt11 x MIR162 x TC1507 x GA21 Corn Hybrids. SSB-036-09	
4	B	McCormick, L., White, J., Sagers, J., Scriven, M., Meehan, M., Meghji, M. (2009). Insecticidal Efficacy of a Bt11 x MIR162 x TC1507 x GA21 Corn Hybrid Against European Corn Borer In the Greenhouse. SSB-154-09	
5	B	McCormick, L., White, J., Sagers, J., Scriven, M., Meehan, M., Meghji, M. (2009). Insecticidal Efficacy of a Bt11 x MIR162 x TC1507 x GA21 Corn Hybrid Against Fall Armyworm in the Greenhouse. SSB-153-09	
6	B	Fan, Y., Ward, K., Raybould, A. (2009). Investigation of the Potential Interaction among the Insecticidal Proteins Cry1Ab, Vip3Aa20 and Cry1F on Insects <i>Ostrinia nubilalis</i> and <i>Spodoptera frugiperda</i> . SSB-035-09	
7	B	Raybould (2009) Environmental Safety Assessment for Bt11 x MIR162 x TC1507 Stacked Corn (Field Corn) Hybrids. SSB-197-09	
8	B	Kurtz, R. (2009) Insect Resistance Management Plan for Bt11 x MIR162 x TC1507 Corn. SSB-101-10	
9	B	Storer, N., Kurtz, R. (2010) Assessment of Cross-Resistance Potential between Cry1F and Cry1Ab or Vip3A in Key Lepidopteran Pests of Corn. IRM 1001	
10	B	Burton, S., Storer, N. (2009) Response of Cry1F-Resistant and Susceptible Fall Armyworm Colonies to Cry1Fa, Cry1Ab, and Vip3A Proteins. DAI 0939	

1 – Categorization code for placement of documents in the Public Docket

Transmittal Document (cont.)

Company Official: Henry York Steiner January 29, 2010

Henry-York Steiner, Ph. D.
Regulatory Affairs Manager

Date

Company Name: Syngenta Seeds, Inc.

Company Contact: Henry-York Steiner / Tel. 919.541.8652

Section I: Administrative Forms

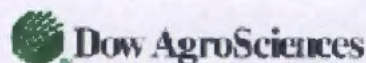
Application for Pesticide Registration (Form 8570-1)

Confidential Statement of Formula (Form 8570-4)

Certification with Respect to Citation of Data (Form 8570-34)

Data Matrix (Form 8570-35)

Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268-1054



November 6, 2009

USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Mail code: 7511P
Washington, DC 20460

Attn: Mr. Mike Mendelsohn

Letter of Authorization for Use of Regulatory Data

We hereby confirm that Agrigenetics, Inc. d/b/a Mycogen Seeds c/o Dow AgroSciences LLC, on behalf of itself and its affiliates, (collectively, "DAS") irrevocably authorize the USEPA to refer to, use or otherwise rely on data previously submitted by DAS in support of the registration, approval or clearance of the following specific product:

- *Insect-Resistant, Glufosinate-Tolerant maize containing B.t. Cry1F Event TC1507 (DAS-01507-1);*

for the purpose of obtaining, maintaining or supporting regulatory or governmental approval or clearance for Syngenta Seeds and its affiliates (collectively "Syngenta") by the USEPA regulatory agency to support a request by Syngenta for the combined trait product, Bt11 x MIR162 x TC1507 x GA21 maize.

We further authorize Syngenta to present this letter to all competent regulatory authorities in connection with seeking such approval and authorize all such regulatory authorities to rely on this letter.

This authorization is limited to authorizing the USEPA to reference and use previously submitted data in support of the registration, approval or clearance of the specific product described herein. This authorization shall not be construed as authorization for the USEPA to use or consider said data, directly or indirectly, in support of any other application by Syngenta relating to any other product or any application submitted by any other applicant. In addition, this authorization shall not be construed as an authorization to release the data to Syngenta, or for Syngenta to possess or review the data. DAS does not release any data for any use not specifically stated herein.

If you require further information, please contact the undersigned at 317-337-3504.

Sincerely,

A handwritten signature in black ink, appearing to read "Laura Tagliani", followed by a horizontal line.

Laura Tagliani
Global Regulator Leader - Corn Traits
Dow AgroSciences LLC



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number:

Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., RTP, NC 27709 (919)
541-8652

EPA Registration Number / File Symbol:

67979-

Active Ingredient(s) and/or representative test compound(s): *B.t. Cry1Ab, Vip3Aa20 proteins and Cry1F and the genetic material necessary for their production in Bt11 x MIR162 x TC1507 corn*

Date:

January 29, 2010

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158:

Terrestrial field crop

Product Name:

Bt11 x MIR162 x TC1507

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]



I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel, or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature

Date

January 29, 2010

Typed or Printed Name and Title

Henry-York Steiner, Regulatory Affairs
Manager



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: January 29, 2010

EPA Reg. No./File Symbol: 67979-

Page 1 of 2

Applicant's/Registrant's Name & Address:

Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., Research Triangle Park, NC 27709

Product: Bt11 x MIR162 x TC1507 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab, Vip3Aa20 and Cry1F proteins and the genetic material necessary for their production in Bt11 x MIR162 x TC1507 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Volumes Specifically Supporting the Combined Plant-Incorporated Protectants in the New Product, Bt11 x MIR162 x TC1507 Corn

N/A	Steiner, H-Y. (2009). Administrative materials in support of the application for registration of the Cry1Ab, Vip3Aa20 and Cry1F plant-incorporated protectants in Bt11 x MIR162 x TC1507 corn	N/A	Syngenta Seeds, Inc.	OWN	Volume 1 of this submission
151-20, 151-21, 151-22, 151-26 885.1100, 885.1200, 885.1300, 885.2100	Burroughs, J., Long, N. (2009). Event Bt11 x MIR162 x TC1507 x GA21 Corn: Comparative Southern Blot Analysis. SSB-106-10	N/A	Syngenta Seeds, Inc.	OWN	Volume 2 of this submission
151-23, 151-25, 151-26, 153-4 885.1400, 885-1500, 885.2200, 885.2400, 885.2500	Bednarcik, M. (2009) Comparison of Transgenic Protein Concentrations in Event Bt11, Event MIR162, Event TC1507, Event GA21, and Bt11 x MIR162 x TC1507 x GA21 Corn Hybrids. SSB-036-09	N/A	Syngenta Seeds, Inc.	OWN	Volume 3 of this submission
N/A	McCormick, L., White, J., Sagers, J., Scriven, M., Meehan, M., Meghji, M. (2009). Insecticidal Efficacy of a Bt11 x MIR162 x TC1507 x GA21 Corn Hybrid Against European Corn Borer In the Greenhouse. SSB-154-09	N/A	Syngenta Seeds, Inc.	OWN	Volume 4 of this submission
N/A	McCormick, L., White, J., Sagers, J., Scriven, M., Meehan, M., Meghji, M. (2009). Insecticidal Efficacy of a Bt11 x MIR162 x TC1507 x GA21 Corn Hybrid Against Fall Armyworm in the Greenhouse. SSB-153-09	N/A	Syngenta Seeds, Inc.	OWN	Volume 5 of this submission
OPPTS 885-4340	Fan, Y., Ward, K., Raybould, A. (2009). Investigation of the Potential Interaction among the Insecticidal Proteins Cry1Ab, Vip3Aa20 and Cry1F on Insects <i>Ostrinia nubilalis</i> and <i>Spodoptera frugiperda</i> . SSB-035-09	N/A	Syngenta Seeds, Inc.	OWN	Volume 6 of this submission
Signature 			Name and Title Henry-York Steiner, Regulatory Affairs Mgr.	Date January 29, 2010	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



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Form Approved OMB No. 2070-0060

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Washington, D.C. 20460

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DATA MATRIX

Date: January 29, 2010

EPA Reg. No./File Symbol: 67979-

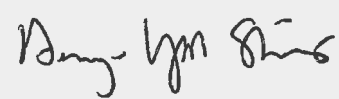
Page 2 of 2

Applicant's/Registrant's Name & Address:

Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., Research Triangle Park, NC 27709

Product: Bt11 x MIR162 x TC1507 Corn

Ingredient *Bacillus thuringiensis* CryIAb, Vip3Aa20 and Cry1F proteins and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885. Group D	Raybould (2009) Environmental Safety Assessment for Bt11 x MIR162 x TC1507 Stacked Corn (Field Corn) Hybrids. SSB-197-09	N/A	Syngenta Seeds, Inc.	OWN	Volume 7 of this submission
N/A	Kurtz, R. (2009) Insect Resistance Management Plan for Bt11 x MIR162 x TC1507 Corn. SSB-101-10	N/A	Syngenta Seeds, Inc.	OWN	Volume 8 of this submission
N/A	Storer, N., Kurtz, R. (2010) Assessment of Cross-Resistance Potential between Cry1F and Cry1Ab or Vip3A in Key Lepidopteran Pests of Corn. IRM 1001	N/A	Syngenta Seeds, Inc.	PER	Volume 9 of this submission
N/A	Burton, S., Storer, N. (2009) Response of Cry1F-Resistant and Susceptible Fall Armyworm Colonies to Cry1Fa, Cry1Ab, and Vip3A Proteins. DAI 0939	N/A	Syngenta Seeds, Inc.	PER	Volume 10 of this submission
Signature 			Name and Title Henry-York Steiner, Regulatory Affairs Mgr.	Date January 29, 2010	

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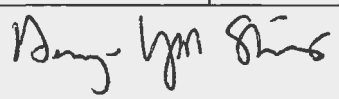
Form Approved OMB No. 2070-0060

401 M Street, S.W.

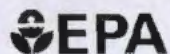
Washington, D.C. 20460

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DATA MATRIX

Date: January 29, 2010			EPA Reg. No./File Symbol: 67979-12		Page 1 of 5
Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., Research Triangle Park, NC 27709			Product: Bt11 x MIR162 Corn		
Ingredient <i>Bacillus thuringiensis</i> Cry1Ab protein and Vip3Aa20 proteins and the genetic material necessary for their production in Bt11 x MIR162 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Huber S. (2009) Administrative Materials for the Responses to the Terms and Conditions (90-day) for the Registrations of Bt11 x MIR162 corn (67979-12) and Bt11 x MIR162 x MIR604 corn (67979-13)	477526-00	Syngenta Seeds, Inc.	OWN	Submission dated May 12, 2009
151-20, 151-21, 151-22, 151-26 885.1100, 885.1200, 885.1300, 885.2100	Guyer D. (2009) Description of the IRM Compliance and Stewardship Requirements for Bt11 X MIR162 Corn	477526-01	Syngenta Seeds, Inc.	OWN	Submission dated May 12, 2009
151-23, 151-25, 151-26, 153-4 885.1400, 885.1500, 885.2200, 885.2400, 885.2500	Guyer D. (2009) Description of the IRM Compliance and Stewardship Requirements for Bt11 X MIR162 X MIR604 Corn	477526-02	Syngenta Seeds, Inc.	OWN	Submission dated May 12, 2009
885. Group D	Kurtz R. (2009) The Vip3Aa20 Resistance Monitoring and Remedial Action Plan for Bt11 X MIR162 and Bt11 X MIR162 X MIR604 and Inclusion of Bt11 x MIR162 X MIR604 into the mCry3A Resistance Monitoring Program	477526-03	Syngenta Seeds, Inc.	OWN	Submission dated May 12, 2009
Signature 			Name and Title Henry-York Steiner, Ph. D. Regulatory Affairs Mgr.		Date January 29, 2010

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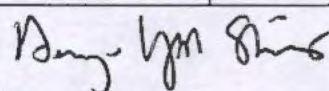


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
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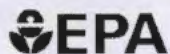
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Date: January 29, 2010			EPA Reg. No./File Symbol: 67979-12		Page 2 of 5
Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., Research Triangle Park, NC 27709			Product: Bt11 x MIR162 Corn		
Ingredient <i>Bacillus thuringiensis</i> Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in Bt11 x MIR162 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Huber S. (2008) Administrative Materials: Supplemental information to the Applications for Registration of the Plant-incorporated Protectants Bt11 x MIR162 (67979-RE) and Bt11 x MIR162 x MIR604 (67979-RG) corn.	476049-00	Syngenta Seeds, Inc.	OWN	Submission dated November 21, 2009
N/A	Huber, S., Graser, G., and D. Ward (2008), Response to Data Deficiencies Noted for the Bt11 x MIR162 and Bt11 x MIR162 x MIR604 Applications for Registration	476049-01	Syngenta Seeds, Inc.	OWN	Submission dated November 21, 2009
N/A	Macdonald, J. 2009. Quantification of Transgenic Proteins in Maize Tissue of Bt11 x MIR162 Sweet Corn and Bt11 x MIR162 Field Corn. Report No. SSB-020-09	478820-01	Syngenta Seeds, Inc.	OWN	Submission dated October 9, 2009
Signature 			Name and Title Henry-York Steiner, Ph. D. Regulatory Affairs Mgr.		Date January 29, 2010

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Applicant's/Registrant's Name & Address:

Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., Research Triangle Park, NC 27709

Product: Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in Bt11 x MIR162 corn

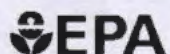
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Dunder, E. (2007). Administrative materials in support of the application for registration of the Cry1Ab and Vip3Aa20 plant-incorporated protectants in Bt11 x MIR162 corn	471374-00	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
151-20, 151-21, 151-22, 151-26 885.1100, 885.1200, 885.1300, 885.2100	Deframond, K. (2007). Comparative Southern analysis of a Bt11 x MIR162 x GA21 maize hybrid with the individual Bt11, MIR162 and GA21 event hybrids. SSB-111-07	47137401	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
151-23, 151-25, 151-26, 153-4 885.1400, 885-1500, 885.2200, 885.2400, 885.2500	McDonald, J. (2007). Comparison of transgenic protein expression in event Bt11, event MIR162, event GA21 and stacked Bt11 x MIR162 x GA21 maize (corn) hybrids. SSB-010-07	47137402	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
885. Group D	Raybould, A. (2007). The Environmental Fate and Potency of the Insecticidal Proteins Cry1Ab and Vip3Aa20 in Bt11 x MIR162 Stacked Maize Hybrids. SSB-524-07	47137403	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
N/A	White, J., Sagers, J. and M. Meghji (2007). European Corn Borer Tolerance of a Bt11 x MIR162 Stacked Field Corn (Maize) Hybrid in the Field. SSB-512-07	471531-01	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
N/A	White, J., Sagers, J. and M. Meghji (2007). Corn Ear Worm Tolerance of a Bt11 x MIR162 Stacked Field Corn (Maize) Hybrid in the Field. SSB-514-07	471531-02	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007

Signature

Name and Title
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Regulatory Affairs Mgr.Date
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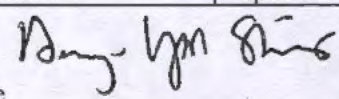
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., Research Triangle Park, NC 27709			Product: Bt11 x MIR162 Corn		
Ingredient <i>Bacillus thuringiensis</i> Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in Bt11 x MIR162 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	White, J., Sagers, J. and M. Meghji (2007). Fall Army Worm Tolerance of a Bt11 x MIR162 Stacked Field Corn (Maize) Hybrid in the Field. SSB-516-07	471531-03	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
N/A	Dunder, E. and Kurtz, R.. (2007) Insect Resistance Management Considerations for Bt11 X MIR162 Corn. SSB-519-07	471374-07	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
N/A	E. Dunder (2007). Reprints for Selected References Cited in Reports Comprising This Application. Bt11x162-EPA-1-VOL9	471374-08	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
N/A	E. Dunder (2007). Reprints for Selected References Cited in Reports Comprising This Application. Bt11x162-EPA-1-VOL10	471374-09	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
N/A	E. Dunder (2007). Reprints for Selected References Cited in Reports Comprising This Application. Bt11x162-EPA-1-VOL11	471374-10	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
	Ward, D. and D. Vlachos (2007). Public interest assessment supporting registration of MIR162, Bt11xMIR162, and Bt11xMIR162xMIR604 maize. Report No. SSB-518-07	471378-19	Syngenta Seeds, Inc.	OWN	Volume 20 of MIR162 submission dated May 17, 2007
OPPTS 885-4340	O'Reilly, D. (2006). Bioassay for interactions between Vip3A and full-length Cry1Ab in <i>Heliothis virescens</i> (Lepidoptera: Noctuidae). Syngenta Seeds Biotechnology Report No. SSB-155-05.	470176-21	Syngenta Seeds, Inc.	OWN	Submitted December 14, 2006
Signature 			Name and Title Henry-York Steiner, Ph. D. Regulatory Affairs Mgr.		Date January 29, 2010

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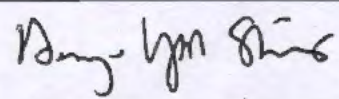


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Date: January 29, 2010		EPA Reg. No. / File Symbol: 67979-12		Page 5 of 5	
Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., 3054 E. Cornwallis Rd., P.O. Box 12257, Research Triangle Park, NC 27709		Product: Bt11 x MIR162 Corn			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in Bt11 x MIR162 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 885-4340	O'Reilly, D. (2006). Bioassay for interactions between Vip3A and full-length Cry1Ab in <i>Helicoverpa zea</i> (Lepidoptera: Noctuidae). Syngenta Seeds Biotechnology Report No. SSB-155-06.	47017622	Syngenta Seeds, Inc.	OWN	Submitted December 14, 2006
885. Group D	Raybould, A. (2006). Environmental safety assessment of insecticidal proteins in MIR162 maize and in Bt11xMIR162 and Bt11xMIR162xMIR604 stacked maize hybrids.	468648-12	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
885.4340	Teixeira, D. (2002). Assessment of chronic toxicity of VIP3A maize (corn) pollen and VIP3A/Cry1Ab maize pollen to the pink-spotted lady beetle (<i>Coleomegilla maculata</i>). 1781.6623	457665-09	Syngenta Seeds, Inc	OWN	Submission dated September 24, 2002
885.4340	Privalle, L. (2002). Impact of VIP3A and Cry1Ab transgenic maize (corn) leaf tissue on 28-day survival and reproduction of <i>Collembola (Folsomia candida)</i> . SSB-006-01	458358-10	Syngenta Seeds, Inc	OWN	Submission dated December 23, 2002
Signature 		Name and Title Henry-York Steiner, Ph. D. Regulatory Affairs Mgr.		Date January 29, 2010	

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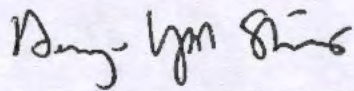
Date: January 29, 2010	EPA Reg. No. / File Symbol: Dow AgroSciences [DAS]: 68467-2; Pioneer Hybrid: 29964-3	Page 1 of 1
Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., Research Triangle Park, NC 27709		Product: TC1507 Corn

Ingredient *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Volumes Specifically Supporting the Cry1F Plant-Incorporated Protectant in TC1507 Corn

N/A	All data volumes pertaining to Herculex I Insect Protected Corn (Cry1F) including, but not limited to, data volumes relating to Product Characterization, Residue and Human Safety, Environmental Safety, Environmental Fate, Insect Resistance Management, Detection Methods, Stewardship and Public Interest.	N/A	DOW AgroSciences, Inc.	PER	Submitted from November 15, 1999 to present

Signature 	Name and Title Henry-York Steiner, Regulatory Affairs Mgr.	Date January 29, 2010
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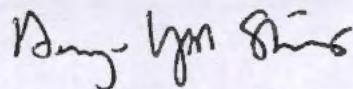
Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., Research Triangle Park, NC 27709

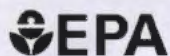
Product: Bt11 x MIR162 x TC1507 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab, Vip3Aa20 and Cry1F proteins and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Volumes Specifically Supporting the Combined Plant-Incorporated Protectants in the New Product, Bt11 x MIR162 x TC1507 Corn					
			Syngenta Seeds, Inc.	OWN	Volume 1 of this submission
			Syngenta Seeds, Inc.	OWN	Volume 2 of this submission
			Syngenta Seeds, Inc.	OWN	Volume 3 of this submission
			Syngenta Seeds, Inc.	OWN	Volume 4 of this submission
			Syngenta Seeds, Inc.	OWN	Volume 5 of this submission
			Syngenta Seeds, Inc.	OWN	Volume 6 of this submission

Signature

Name and Title
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Regulatory Affairs Mgr.Date
January 29, 2010

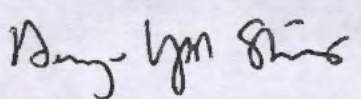


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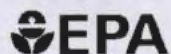
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., Research Triangle Park, NC 27709		Product: Bt11 x MIR162 x TC1507 Corn			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ab, Vip3Aa20 and Cry1F proteins and the genetic material necessary for their production in corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc.	OWN	Volume 7 of this submission
			Syngenta Seeds, Inc.	OWN	Volume 8 of this submission
			Syngenta Seeds, Inc.	PER	Volume 9 of this submission
			Syngenta Seeds, Inc.	PER	Volume 10 of this submission
Signature 			Name and Title Henry-York Steiner, Regulatory Affairs Mgr.		Date January 29, 2010

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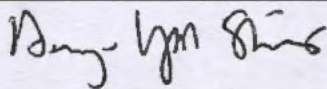


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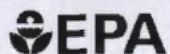
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., Research Triangle Park, NC 27709		Product: Bt11 x MIR162 Corn			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in Bt11 x MIR162 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		477526-00	Syngenta Seeds, Inc.	OWN	Submission dated May 12, 2009
		477526-01	Syngenta Seeds, Inc.	OWN	Submission dated May 12, 2009
		477526-02	Syngenta Seeds, Inc.	OWN	Submission dated May 12, 2009
		477526-03	Syngenta Seeds, Inc.	OWN	Submission dated May 12, 2009
Signature 			Name and Title Henry-York Steiner, Ph. D. Regulatory Affairs Mgr.		Date January 29, 2010

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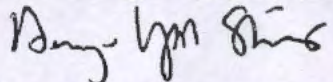
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Ingredient <i>Bacillus thuringiensis</i> Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in Bt11 x MIR162 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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		476049-01	Syngenta Seeds, Inc.	OWN	Submission dated November 21, 2009
		478820-01	Syngenta Seeds, Inc.	OWN	Submission dated October 9, 2009
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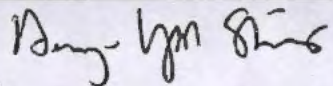


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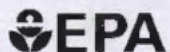
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		471374-00	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
		47137401	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
		47137402	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
		47137403	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
		471531-01	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
		471531-02	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
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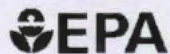
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		471374-08	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
		471374-09	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
		471374-10	Syngenta Seeds, Inc.	OWN	Submitted May 17, 2007
		471378-19	Syngenta Seeds, Inc.	OWN	Volume 20 of MIR162 submission dated May 17, 2007
		470176-21	Syngenta Seeds, Inc.	OWN	Submitted December 14, 2006

Signature

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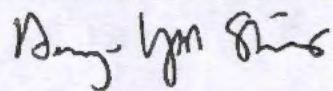


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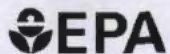
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DATA MATRIX

Date: January 29, 2010		EPA Reg. No. / File Symbol: 67979-12		Page 5 of 5	
Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., Research Triangle Park, NC 27709		Product: Bt11 x MIR162 Corn			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in Bt11 x MIR162 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		47017622	Syngenta Seeds, Inc.	OWN	Submitted December 14, 2006
		468648-12	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
		457665-09	Syngenta Seeds, Inc	OWN	Submission dated September 24, 2002
		458358-10	Syngenta Seeds, Inc	OWN	Submission dated December 23, 2002
Signature 			Name and Title Henry-York Steiner, Ph. D. Regulatory Affairs Mgr.		Date January 29, 2010

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DATA MATRIX

Date: January 29, 2010	EPA Reg. No. / File Symbol: Dow AgroSciences [DAS]: 68467-2; Pioneer Hybrid: 29964-3	Page 1 of 1
Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, 3054 E. Cornwallis Rd., Research Triangle Park, NC 27709		Product: TC1507 Corn

Ingredient *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Volumes Specifically Supporting the Cry1F Plant-Incorporated Protectant in TC1507 Corn

	DOW AgroSciences, Inc.	PER	Submitted from November 15, 1999 to present

Signature 	Name and Title Henry-York Steiner, Regulatory Affairs Mgr.	Date January 29, 2010
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Section II. Summary of the Application

Syngenta has developed the combined insecticidal trait product Bt11 x MIR162 x TC1507 corn. The Bt11 x MIR162 x TC1507 stacked product was developed by combining the transgenic traits in Event Bt11 corn, which expresses a truncated *Bacillus thuringiensis* (*Bt*) Cry1Ab protein for control of certain lepidopteran pests, with Event MIR162 corn, which expresses a *Bt* Vip3Aa20 protein for control of certain lepidopteran pests and TC1507 corn, which expresses a *Bt* Cry1F protein for control or suppression of certain lepidopteran pests. The genes in these separate transgenic products were combined into the same corn variety through conventional breeding. Bringing these three insecticidal traits together in the same plant offers growers a convenient, reliable, and low-risk approach for limiting crop damage caused by a number of the major insect pests of corn.

This application for a FIFRA Section 3 registration of the active ingredients in Bt11 x MIR162 x TC1507 corn is accompanied by data volumes that describe the results of molecular characterization, protein level determination, product efficacy, environmental risk and resistance management studies. These studies substantiate the equivalence of Bt11 x MIR162 x TC1507 corn and corn derived from the component transformation events and non-transgenic control corn. This application further relies upon studies previously submitted to EPA for Cry1Ab, Vip3Aa20 and Cry1F (including public interest assessments), which are cited in the data matrix and cited with permission from DOW Agrisciences (DAS). The Bt11 x MIR162 x TC1507 corn product will be marketed in varieties also containing Event GA21, which expresses a *dmepsps* gene conferring tolerance to glyphosate containing herbicides. This Bt11 x MIR162 x TC1507 x GA21 plant material was used in the majority of the studies submitted with this application.

Bt11 x MIR162 X TC1507 Corn

[Alternate brand name: *Agrisure*[®] *Viptera*[™] 3220 Refuge renew]

OECD Unique Identifier: SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1

Plant-incorporated protectant: Cry1Ab, Vip3Aa20 and Cry1F proteins for control of corn borers and other lepidopteran pests

This product is effective in controlling corn leaf, stalk, and ear damage caused by certain lepidopteran pests.

Active Ingredients:

Bacillus thuringiensis Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1).....≤0.00103%*

Bacillus thuringiensis Vip3Aa20 insecticidal protein and the genetic material necessary for its production (via elements of vector pNOV1300) in MIR162 corn event (SYN-IR162-4)..... ≤0.00256%*

Bacillus thuringiensis Cry1F delta-endotoxin protein and the genetic material necessary for its production (via elements of vector PHI8999) in corn event TC1507 (DAS-Ø15Ø7-1)≤0.00077%*

Other Ingredients:

A marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1) and (via elements of vector PHI8999) in corn event TC1507 (DAS-Ø15Ø7-1).....≤0.00017%*

A marker protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (SYN-IR162-4)...≤0.00025%*

*Percent (wt/wt) of whole plant on a dry weight basis

CAUTION KEEP OUT OF REACH OF CHILDREN

EPA Registration No. 67979-
EPA Establishment No. 66736-NC-01

Syngenta Seeds, Inc.
P.O. Box 12257
3054 East Cornwallis Rd.
Research Triangle Park, NC 27709

[™] Agrisure is a trademark of a Syngenta Group company

[™] Viptera is a trademark of a Syngenta Group company

DIRECTIONS FOR USE

It is a violation of federal law to use this product in any manner inconsistent with this labeling. All corn seed that contains the plant-incorporated protectant sold or distributed by Syngenta Seeds, Inc. or its distributors must be accompanied by informational material (e.g., a bag tag) indicating the registration number (67979-) and the active ingredients, and stipulating that growers read the Grower Guide (or equivalent guidance) prior to planting the seed.

Insects Controlled or Suppressed

Field corn has been genetically transformed to produce the insecticidal proteins, Cry1Ab, Vip3Aa20 and Cry1F, for control or suppression of the following lepidopteran insects:

European corn borer (*Ostrinia nubilalis*)
Southwestern corn borer (*Diatraea grandiosella*)
Southern cornstalk borer (*Diatraea crambidoides*)
Corn earworm (*Helicoverpa zea*)
Fall armyworm (*Spodoptera frugiperda*)
Beet armyworm (*Spodoptera exigua*)
Black cutworm (*Agrotis ipsilon*)
Western bean cutworm (*Striacosta albicosta*)
Sugarcane borer (*Diatraea saccharalis*)
Lesser cornstalk borer (*Elasmopalpus lignosellus*)
Dingy Cutworm (*Feltia jaculifera*)
Common stalk borer (*Papaipema nebris*)

Insect Resistance Management

The following information regarding commercial production Bt11 x MIR162 x TC1507 corn must be included in the Grower Guide (or equivalent).

- Specifically, growers must plant a structured refuge of at least 5% non-*Bt* corn (20% in cotton growing* regions) and/or nonlepidopteran-resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least four consecutive rows wide.
- Insecticide treatments for control of European corn borer (ECB), corn earworm (CEW), southwestern corn borer (SWCB), and other lepidopteran pests listed on the label, grower

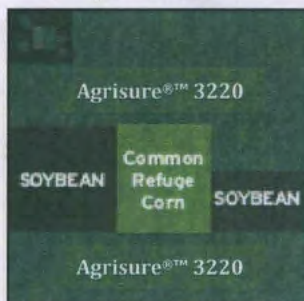
guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran-resistant *Bt* corn refuges.

Cotton-Growing* Regions Required to Plant 20% Refuge Corn

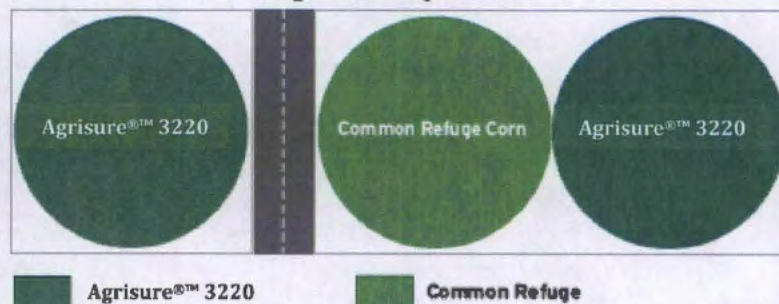
Alabama – all counties
Arkansas – all counties
Florida – all counties
Georgia – all counties
Louisiana – all counties
Mississippi – all counties
Missouri – counties of:
 Dunklin Scott
 New Madrid Stoddard
 Pemiscot
North Carolina – all counties
Oklahoma – counties of:
 Beckham Jackson
 Caddo Kay
 Comanche Kiowa
 Custer Tillman
 Greer Washita
 Harmon
South Carolina – all counties
Tennessee – counties of:
 Carroll Haywood
 Chester Lake
 Crockett Lauderdale

Dyer Lincoln
 Fayette Madison
 Franklin Obion
 Gibson Rutherford
 Hardeman Shelby
 Hardin Tipton
Texas – all counties EXCEPT:
 Carson Lipscomb
 Dallam Moore
 Hansford Ochiltree
 Hartley Roberts
 Hutchinson Sherman
 (NOTE: these counties are
 required to plant at least
 5% refuge corn)
Virginia – counties of:
 Dinwiddie Southampton
 Franklin City Suffolk City
 Greensville Surrey
 Isle of Wight Sussex
 Northampton
 * Identified by EPA as cotton
 growing areas.

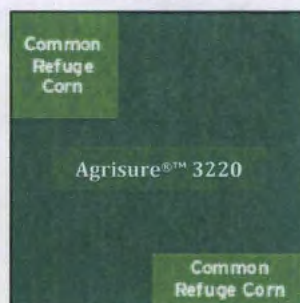
Adjacent Fields



Separated By a Road



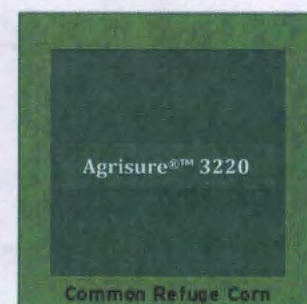
Blocks



Adjacent Multiple Rows



Perimeter



Section IV. Residue Data

The *Bacillus thuringiensis* Bt Cry1Ab δ -endotoxin protein and the genetic material necessary for its production in all plants is exempt from tolerance requirements in all plants under 40 CFR §174.511.

An exemption from the requirement of a tolerance for Vip3Aa proteins in corn and cotton has been established under 40 CFR § 174.501. The exemption from the requirement of a tolerance for residues of Vip3Aa proteins is inclusive of the Vip3Aa20 insecticidal protein and its use in corn.

An exemption from the requirement of a tolerance for *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production in corn (non-Event specific) was granted under 40 CFR §174.520.

The marker substance in MIR162, phosphomannose isomerase (PMI), and the genetic material necessary for its production in all plants is exempt from the requirement of a tolerance under 40 CFR §174.527.

The marker substance in Bt11 and TC1507 corn, phosphinothricin acetyltransferase (PAT) enzyme, and the genetic material necessary for its production in all plants is exempt from the requirement of a tolerance under 40 CFR §174.522.

Section VI. Nontarget Organism Data

Studies have been conducted by Syngenta and others that adequately characterize the potential hazards of Bt11 corn, MIR162 corn and TC1507 corn. These studies were previously submitted to EPA and are referenced by MRID in the Administration volumes cited in the Data Matrix section included in this application for registration.

Section VII. Toxicology Data

Not Applicable to this Application for Registration

Section VIII. Efficacy Data

Data demonstrating the efficacy of Bt11 and TC1507 plants for limiting corn borer feeding damage have previously been submitted to EPA and are referenced by MRID in the Administration volumes cited in the Data Matrix section included in this application for registration.

Data demonstrating the efficacy of MIR162 plants for limiting corn earworm and fall armyworm feeding damage have previously been submitted to EPA and are referenced by MRID in the Administration volumes cited in the Data Matrix section included in this application for registration.

Volumes 4 and 5 of this application compare the efficacy of the combined trait product Bt11 x MIR162 x TC1507 to Bt11, MIR162 and TC1507 corn for corn borer feeding damage (Vol. 4) and fall armyworm feeding damage (Vol. 5).

